BioProcess International Asia

26-28 February 2019
Hilton Tokyo Bay
Tokyo, Japan

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Jerry Yang
SVP, Product and Process Development,
GM, CDMO Business Unit,
Hangzhou Just Biotherapeutics Ltd., *China*

Toshio Fujimoto, M.D., MBA
General Manager, Shonan Health Innovation Park, Takeda Pharmaceutical Company Limited, *Japan*

Hidenari Yamada
Department Manager,
API Process Development,
Chugai Pharmaceutical,
Japan

Association Partner:
JBA
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Co-located with
- AsiaTIDES: Oligonucleotide & Peptide Therapeutics
- Cell Therapy Manufacturing Asia
- Antibody Engineering & Therapeutics Asia

ACCELERATE YOUR BIOLOGICAL PRODUCTS TOWARDS COMMERCIAL SUCCESS

INNOVATIVE SCIENCE

Understand critical trends across the entire bioprocessing spectrum by hearing new data and innovative case studies from top global biopharmaceutical companies across Asia, Europe and USA.

INDUSTRY LEADING TECHNOLOGIES

Drive down your development and manufacturing costs by accessing live product demonstrations from global CROs, CMOs and suppliers devoted to serving the biopharmaceutical market.

GLOBAL NETWORKING

Grow your business by connecting with global scientists and senior bioprocessing executives working across upstream, downstream, analytical and commercial manufacturing.

PRE-CONFERENCE WORKSHOP #1:
PREPARING FOR FDA AND EMA CGMP COMPLIANCE INSPECTIONS

Scott Wheelwright, Ph.D., Principal Consultant, **Complya Asia Co., Ltd.,** *China*

Objective:

The objective of this course is to provide participants with the information they need to implement and operate a Quality Management System that meets the expectations of international regulatory agencies.

Trainer:

Dr. Wheelwright is founder of Complya Asia Co., Ltd., a consultancy focused on improving the quality of pharmaceutical practice in China. Dr. Wheelwright was founding Chief Operations Officer with Innovent Biologics, one of the leading biopharmaceutical development companies in China.

Dr. Wheelwright has been an executive officer in several biotech startups, and has supervised the areas of manufacturing, process development, compliance, quality assurance, quality control, validation, engineering and facilities. He has worked as a researcher in the laboratory and has led the development of several products that are now on the market. He has led the construction of multiple manufacturing facilities that meet the international compliance requirements for current Good Manufacturing Practice (cGMP).

Dr. Wheelwright has over 30 years experience in solving the challenges companies encounter when bringing biotech, pharmaceutical, and other medical products out of research and into the commercial marketplace.

Overview:

Developing and implementing Quality programs that meet international expectations is a challenge for many companies. Part of the challenge is understanding the requirements of foreign regulatory agencies. Another challenge is changing the way of thinking of employees to recognize how they can always be in compliance (yes, this is possible!).

In this training you will be taught what you need to do to ensure your quality system is in compliance with international standards for Quality Assurance. We will go through each of the Quality Management Systems and identify common issues and how to overcome them. We will discuss the problems companies face in presenting their compliance performance to inspectors and how to help inspectors understand our true level of compliance.

This hands-on course will provide you with an understanding of:

- How to work with FDA and EMA inspectors
- How to develop Quality Management Systems that meet international requirements
  - QMS document requirements
  - Operating procedure requirements
  - Facility and equipment requirements
  - Quality Control requirements
- What is compliance and what does it mean to be in compliance
- What are the requirements for compliance
- How do we develop a quality mindset among all levels of employees

PRE-CONFERENCE WORKSHOP #2:
THE ESSENTIALS OF TECHNOLOGY TRANSFER

Richard Dennett, Senior Director Regulatory Affairs CMC, **PPD,** *France*

Virtually every company will need to outsource certain factors over the course of its drug product development; whether it be analytical and process development, cGMP contract manufacture, characterization and viral clearance testing, validation, regulatory support etc. This is underpinned by Technology Transfer.

Principal junctures of Technology Transfer can occur between pre-clinical to first into human (FIH), successive clinical stages and through to commercial manufacture.

Technology transfer elements can be complex and in today's fast-moving field of drug development there can be no room for error, with associated cost and delay implications. Technology transfer lies directly on the critical path and therefore must be right 'first time'. Demonstration of Product Comparability forms an essential element of certain technology transfer situations and which is essential in ensuring an exacting clinical product and meeting regulatory expectation.

In this workshop we will examine essential technology transfer as it applies to multiple product types (recombinants, biologics, vaccines, cellular and gene therapy products, conjugates etc.) and

- The nature of the challenge
- Strategy
- The 'nuts and bolts' of technology transfer
- Application to different product types recombinants, mAbs, biologics, ATMPs, biosimilars etc.
- Considerations of early and late stage transfers
- Pre-clinical to FIH
- cGMP manufacture
- The importance of the quality target product profile
- Ensuring Product Comparability
- Change control
- Regulatory compliance and health authority expectation
- Managing risk
- Sourcing and selection of a CMO partner
- Project management
- Technical and Quality agreements, protocols and reports
- Dealing with issues and how to get things back on track
- In licensing
- Commercial strategy
- Common pitfalls

The workshop will incorporate a mix of interactive modules, real life case studies, key topic points for discussion plus will provide model examples of actual technical quality agreements, technology transfer protocols and reports.

8:00 *Registration and Morning Coffee*

PLENARY SESSION

8:45 **Chairperson's Opening Remarks and Welcome to BPI Asia**

9:00 **KEYNOTE ADDRESS: Creating Innovation Ecosystem and Hotspot in Shonan, Japan**

Toshio Fujimoto, M.D., MBA, General Manager, Shonan Health Innovation Park, **Takeda Pharmaceutical Company Limited,** *Japan*

9:30 **KEYNOTE ADDRESS: Implementation of Continuous Manufacturing Facility to Increase Flexibility and Capacity – A Case Study of an Antibody Continuous Process Scale-up**

We have established a POD based disposable continuous manufacturing GMP facilities in Hangzhou, China. The innovative design of the facility provides highly flexible and efficient biologics manufacture, with speed and cost advantage. This continuous manufacturing facility is designed to meet all international GMP rules by FDA, EMEA, Japan and cFDA. Two 500L lines are in operation now,and can be expanded to a total of 6x500L capacity within 6-9 months for large scale end to end processing. We will share the issues and challenges for the implementation from a green field to a full GMP operation of the new facility. A case study of technology transfer and scale-up GMP production for FDA IND filing supply will be provided. A case study of continuous perfusion process development of an antibody with a yield of 2 g/L/day will be presented. It is our mission to design and apply innovative technologies to provide biotherapeutics drugs that not only meet international quality standards, but also are affordable to patients in China and around the world.

Jerry Yang, Senior Vice President, Process and Product Development, **Hangzhou Just Biotherapeutics Co.,** *China*

10:00 **PLENARY PANEL DISCUSSION: Next Generation Bioprocessing, Digitalization and Facilities of the Future**

- What do the future strategies for bioprocessing look like?
- Reducing manufacturing footprint through process improvements and changes
- Improving production efficiency, reducing costs and increasing capacity to increase speed to market
- Process intensification
- Evaluating new platforms and technologies for increased flexibility in commercial manufacturing

Panelists:

Weichang Zhou, Ph.D., Chief Technology Officer, Senior Vice President, Biologics Development and Manufacturing, **Wuxi Biologics,** *China*

10:30 *Networking Refreshment Break in the Exhibit & Poster Hall*

	TRACK ONE: CELL LINE DEVELOPMENT AND UPSTREAM PROCESSING	TRACK TWO: DOWNSTREAM PROCESSING
	Cell Line Development and Engineering	**Innovative Approaches and Technologies in Downstream Processing**
11:10	**Chairperson's Remarks**	**Chairperson's Remarks**
11:15	**Accelerating Timelines from Early Candidate Selection to Production Cell Lines** **Thomas Jostock,** Science and Technology Lead / Principal Fellow, **Novartis,** *Switzerland*	**Featured Presentation – Analysis of Economic Drivers for Integrated & Continuous Bioprocessing of mAbs** CASE STUDY NEW DATA **Günter Jagschies, Ph.D.,** Senior Director, Strategic Customer Relations, **GE Healthcare,** *Germany*
11:45	**Target Integration Technology for Bioproducts Manufacturing** Chugai introduced target integration technology in cell line development for manufacturing recombinant therapeutic proteins. To shorten project time line is strongly desired in pharmaceutical industry, however, process of cell line development currently takes at least a few months and is extremely tedious. Target integration-based cell line development is attractive as the plasmid vectors integrate into predetermined active sites in genomes. **Kunihiko Kodaira,** CLD Group Manager, API Process Development Dept., **Chugai Pharmaceutical Co., Ltd.,** *Japan*	**Innovative Strategies for Enhancing HCP Clearance in Clarification and Downstream Processing** CASE STUDY NEW DATA **Benoit Mothes,** DSP Skill Center Head, DSP Breakthrough Technologies Skill Center, BioPharmaceutics Development, **Sanofi,** *France* **Fabien Rousset, Ph.D.,** Head of Bioseparations, Daicel, **Chiral Technologies Europe,** *France*
12:15	**Sponsored Scientific Track Presentation**	**Sponsored Scientific Track Presentation**
12:45	*Luncheon in the Exhibit & Poster Hall*	

	TRACK ONE: CELL LINE DEVELOPMENT AND UPSTREAM PROCESSING	TRACK TWO: DOWNSTREAM PROCESSING
	Upstream Processing – Process Intensification, Perfusion Systems and Cell Culture Media Development	**Innovative Approaches and Technologies in Downstream Processing**
1:55	**Chairperson's Remarks**	**Chairperson's Remarks**
2:00	**Intensification of a Multi-Product Perfusion Platform for Rapid Process Development** The Intensified Perfusion Platform (IPP) at Sanofi has minimized the need for extensive development work and optimization in early stage. Challenges in achieving high cell density and sustainable volumetric productivity, comparisons between fed batch and intensified perfusion, technology readiness for single use bioreactor scale-up, development of perfusion scale down systems, and integration of at-line and online analytics will be discussed. **Shawn Barrett,** Associate Director, **Sanofi R&D,** *USA*	**Overcoming Downstream Challenges for Fc Fusion Proteins** **Ijeoma Ikechukwu,** Senior Scientist, Downstream Process Development, **Patheon**
2:30	**Media Development for Intensified Seed Train Expansion Including N-1 Perfusion** Media composition plays a critical role for biopharmaceutical production as well as seed train expansion. We could show that the right combination of media, specifically designed for their purposes, in a seed train including a perfused N-1 step can increase productivity in the final perfused production step, indicating that specific companion media combinations can increase productivity gains with these intensified process formats. **Mona Bausch,** Scientist in Perfusion Systems R&D, **Merck Life Science,** *Germany*	**Installation Strategies of Single-Use Technologies for Downstream Processing** **Kosuke Takenaka, MSc.,** Principal Scientist, Process and Product Development, **Takeda, Pharmaceutical Company Limited,** *Japan*
3:00	**New Technologies for Improving and Controlling Product Quality, Expression, Timelines and Yield in Upstream Process Development** **Niki Wong,** Principal Research Scientist, **AbbVie Operations Singapore Pte Ltd,** *Singapore*	**Sponsored Scientific Track Presentation**
3:30	*Networking Refreshment Break in the Exhibit & Poster Hall*	
	PLENARY SESSION	
4:00	**Continuous BioManufacturing: Past, Present, and Future** **Sadettin Ozturk, Ph.D.,** Senior Vice President, Process and Analytical Development, **MassBiologics,** *USA*	
4:30	**Continuous Manufacturing in Monoclonal Antibody Development** **Karen Wen, Ph.D.,** President, **Mycenax Biotech Inc.,** *Taiwan* CASE STUDY NEW DATA	
5:00	**iLDC Based Continuous Process, Future Direction on CMC of Next Generation ADCs** **Gang Qin,** President, **GeneQuantum Healthcare (Suzhou) Co., Ltd.,** *China*	
5:30	*Close of Day One and Cocktail Reception in Exhibit Hall*	

8:00	*Registration and Morning Coffee*
9:00	**Chairperson's Opening Remarks**
	PLENARY SESSION
9:10	**KEYNOTE ADDRESS: Designing Cost Effective Next Generation Factory for Biologics – Case Study from Chugai Pharmaceutical Japan** Reducing manufacturing cost is significant for increasing accessibility to biologics for patients. And increasing manufacturing start-up speed and flexibility is a key under an uncertain business environment. This presentation covers concept of Next Generation Factory to aim reduction of manufacturing cost from several hundred dollars to several ten dollars. Key features of the factory are small footprint with continuous manufacturing and automation. **Hidenari Yamada,** Deputy Department Manager of API Process Development Department, **Chugai Pharmaceutical Co., Ltd.,** *Japan* 
9:50	**PANEL DISCUSSION: Market Trends and Implications for Bioprocessing in Asia** • Critical review of the biopharmaceutical market in Asia • Innovation in biopharma pipelines – What can be expected in terms of therapeutic areas and product types • Trends towards in house manufacturing or CDMO? • Single use vs stainless steel facilities • Continuous processing vs fed batch • Impact of biosimilars • Regulatory developments and impact on bioprocessing • Strategies to improve the bioprocessing capabilities in Asia • How is the bioprocessing industry in Asia going to be in 2020? *Moderator:* **Scott Wheelwright, Ph.D.,** Principal Consultant, **Complya Asia Co., Ltd.,** *China*
10:30	*Networking Refreshment Break in the Exhibit & Poster Hall*
	TRACK ONE: ANALYTICAL, QUALITY CONTROL AND SINGLE USE SYSTEMS / **TRACK TWO: TECHNOLOGY TRANSFER AND BIOMANUFACTURING STRATEGIES**
	Real-Time Process Monitoring Methods & Single Use Systems / **Technology Transfer and Scale Up – Case Studies and Lessons Learned**
11:10	**Chairperson's Remarks** / **Chairperson's Remarks**
11:15	**CASE STUDY: Use of Multivariate Data Analytics For Real Time Process Monitoring And Controls** **Denise Tan,** Principal Engineer, Process Development, **Amgen Singapore Manufacturing Pte Ltd,** *Singapore* / **Technology Transfer Lead Time Reduction at Roche** **Joe Runner,** Senior Manufacturing Technical Specialist, Global Technology Acceleration Team, **Genentech,** *USA*
11:45	**PANEL DISCUSSION: Best Practices for Ensuring Quality Control for Single Use Systems** **Panelists:** **Denise Tan,** Principal Engineer, Process Development, **Amgen Singapore Manufacturing Pte Ltd,** *Singapore* / **Re-Purposing Equipment for Scale-Up Capacity at Reduced Cycle Time and Capital Expense** **Paul Kubera,** Vice President, Process Technology, **ABEC, Inc.,** *USA*
12:15	**Sponsored Scientific Track Presentation** / **Sponsored Scientific Track Presentation**
12:45	*Luncheon in the Exhibit & Poster Hall*

	TRACK ONE: ANALYTICAL, QUALITY CONTROL AND SINGLE USE SYSTEMS	TRACK TWO: TECHNOLOGY TRANSFER AND BIOMANUFACTURING STRATEGIES
	Quality Control Methods for Biopharmaceuticals – Challenges and Key Considerations	**Economic Analysis, Drivers, and Strategies in Biomanufacturing**
1:55	**Chairperson's Remarks**	**Chairperson's Remarks**
2:00	**Considerations and Strategies in Creation of GMP Master and Working Cell Banks to Meet FDA, EMA and NMPA Expectations** **Liming Shi,** Senior Director, QC, **CMAB Biopharma Inc.,** *China*	**Economic Analysis and Drivers for Continuous Processing Facilities** **Yuki Abe, Ph.D.,** Senior Consultant Engineer, **Biopharm Services Ltd.,** *United Kingdom*
2:30	**Quality Systems – The Key to Compliance and Ensure Long Term Product Success** **Claudia Lin, Ph.D.,** Founder & CEO, **JADE BioMedical**	**Implementation of BPOG's Biomanufacturing Technology Roadmap: Progress, Challenges and Prospects** **Akihiro Yanagita,** Group Manager, **Chugai**
3:00	*Networking Refreshment Break in the Exhibit & Poster Hall*	
	PLENARY SESSION	
	Regulatory Perspectives - Impact of Evolving Global Regulatory Landscape on Bioprocessing	
3:30	**Regulatory Updates for Successful US IND/BLA Filing for Novel and Biosimilar Products** **Audrey Jia, M.D., Ph.D., M.S.,** exFDA Biological Product Senior CMC Reviewer, Regulatory, **DataRevive LLC,** *USA*	
4:00	**Government Reforms to the Drug Registration Process and How They Affect Biopharmaceutical Manufacturing in China** **Scott Wheelwright, Ph.D.,** Principal Consultant, **Complya Asia Co., Ltd.,** *China*	
4:30	**Regulatory Perspective for Successful ADC Development and Case Studies** CASE STUDY NEW DATA **Wen Jin Wu, Ph.D.,** Senior Investigator, Office of Biotechnology Products, **US Food and Drug Administration (FDA),** *USA*	
5:00	*Close of Main Conference*	

HIGHLIGHT YOUR COMPANY'S EXPERTISE AT BPI ASIA 2019

BPI Asia bridges multiple stages of development to share innovative ideas that improve the cost and quality of process, product development, and manufacturing.

Attendees of BPI Asia will get to experience and influence the paradigm shift of developing and manufacturing biopharmaceuticals through collaborative efforts across departments and stages of development. As a sponsor of BPI Asia, partner with leading bioprocess decision makers in need of solutions towards commercially successful biologics.

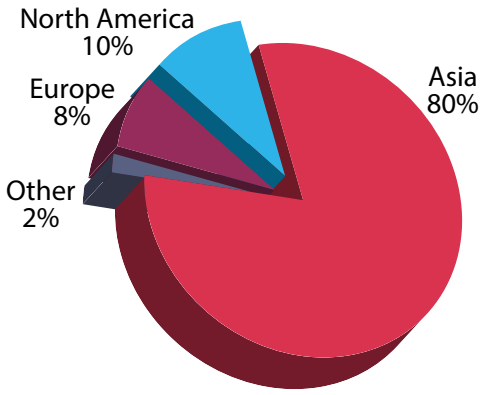
BPI ASIA HIGHLIGHTS

200+
Attendees

8+
Hours of Networking

Over 200 leading scientists, engineers, and executives from across the biopharmaceutical industry will come together for this unique event

BY GEOGRAPHY



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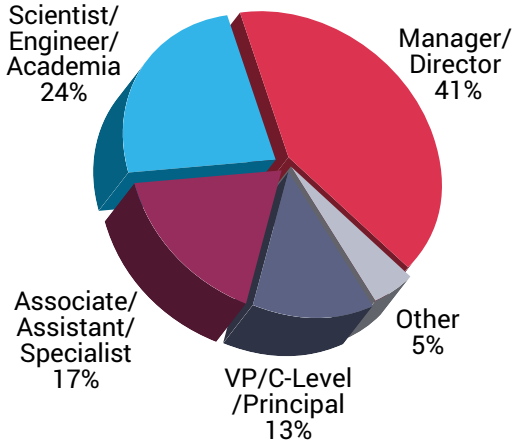

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